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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/523,292

02/03/2005

Guillermo Oliver

SJ-02-0011A

1276

28258

7590

04/18/2007

ST. JUDE CHILDREN'S RESEARCH HOSPITAL
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EXAMINER

HOLLERAN, ANNE L

ART UNIT

PAPER NUMBER

1643

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
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31 DAYS

04/18/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/523,292

Applicant(s)

OLIVER ET AL.

Examiner

Anne L. Holleran

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1643

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-11 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date ____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: ____.

DETAILED ACTION

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions that are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) claim 1-5 (*to the extent the claims are drawn to methods of detecting Prox1 mRNA*), drawn to methods for determining the extent of lymphatic involvement in a tumor, comprising detecting the expression of Prox1 in the tumor.

Group II, claim(s) claims 1-5 (*to the extent the claims are drawn to methods of detecting Prox1 protein*), drawn to methods for determining the extent of lymphatic involvement in a tumor, comprising detection the expression of Prox1 in the tumor.

Group III, claim(s) 6 and 7, drawn to a gene therapy vector comprising a gene encoding a Prox1 protein, and to a method of promoting the development of lymphatic tissue in a subject, comprising administering the gene therapy vector.

Group IV, claim(s) 8-10 (*to the extent the claims are drawn to methods of selecting cells that express Prox1*), drawn to methods of purifying endothelial precursor cells having the potential to develop into lymphatic tissue from a sample of cells.

Group V, claim(s) 8-10, (*to the extent the claims are drawn to methods of selecting cells that express LYVE-1*), drawn to methods of purifying endothelial precursor cells having the potential to develop into lymphatic tissue from a sample of cells.

Group VI, claim(s) 11, (*to the extent the claims are drawn to methods of administering cells that express Prox1*), drawn to methods of administering endothelial precursor cells having the potential to develop into lymphatic tissue from a sample of cells.

Group VII, claim(s) 11, (*to the extent the claims are drawn to methods of administering cells that express LYVE-1*), drawn to methods of administering endothelial precursor cells having the potential to develop into lymphatic tissue from a sample of cells.

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The inventions listed as Groups I-VII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: the feature that is common to the groups I-IV and VI), that of using Prox1 expression as a marker for lymphatic precursor cells, is known in the art as evidenced by the teachings of Wigle (Wigle, J. T. et al., Cell, 98: 769-778, 1999; cited in the IDS). Therefore, the groups lack a corresponding special technical feature that makes a contribution over the prior art as a whole. Furthermore, the feature of groups V and VII appears to be the detection of LYVE-1 as a marker for lymphatic precursor cells, which is not a feature of groups I-IV and VI. This feature also is known in the art as evidenced by the teachings of Kriehuber (Kriehuber, E. et al., J. Exp. Med., 194(6): 797-808, 2001; see abstract), which teaches that LYVE-1 is a molecule that is selectively displayed by lymphatic endothelial cells. Therefore, the use of detection of LYVE-1 does not appear to be a special technical feature that makes a contribution over the prior art as a whole.

The technical feature of group I is: detection of Prox1 mRNA in tumor tissue.

The technical feature of group II is: detection of Prox1 protein in tumor tissue.

The technical feature of group III is: a gene therapy vector comprising a gene encoding a Prox1 protein.

The technical feature of group IV is: purifying endothelial cells by selecting for cells that express Prox1.

The technical feature of group V is: purifying endothelial cells by selecting for cells that express LYVE-1.

The technical feature of group VI is: administering to a subject endothelial cells that express Prox1.

The technical feature of group VII is: administering to a subject endothelial cells that express LYVE-1.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne Holleran, whose telephone number is (571) 272-0833. The examiner can normally be reached on Monday through Friday from 9:30 am to 5:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, can be reached on (571) 272-0832. Any inquiry of a general nature or relating to the

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status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. The faxing of such papers must conform to the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Official Fax number for Group 1600 is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll free).

Anne L. Holleran
Patent Examiner
April 12, 2007



LARRY R. HELMS, PH.D.
SUPERVISORY PATENT EXAMINER